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10/759,904	01/16/2004	Eric J. Beckman	02-012	1518
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary						
		10/759,904	BECKMAN ET AL.			
Omo	o rionon cummary	Examiner	Art Unit			
The MAI	LINC DATE of this communication and	James W. Rogers, Ph.D.	1618			
Period for Reply	LING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
WHICHEVER II  - Extensions of time after SIX (6) MONT  - If NO period for rep  - Failure to reply with Any reply received	O STATUTORY PERIOD FOR REPLY S LONGER, FROM THE MAILING DAM may be available under the provisions of 37 CFR 1.13 "HS from the mailing date of this communication. Hy is specified above, the maximum statutory period whin the set or extended period for reply will, by statute, by the Office later than three months after the mailing adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	the mailing date of this communication.  D (35 U.S.C. § 133).			
Status						
1) Responsi	ve to communication(s) filed on 11 Oc	c <u>tober 2007</u> .				
2a) ☐ This action	This action is FINAL. 2b)⊠ This action is non-final.					
3) Since this	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Cla	ims					
4a) Of the 5) ☐ Claim(s) ☐ Claim(s) 7) ☐ Claim(s)	1 and 3-103 is/are pending in the apple above claim(s) 3-14,17,27-68,70-103 is/are allowed.  1,3-12,15,16,18-26 and 69 is/are rejection is/are objected to.  are subject to restriction and/or	is/are withdrawn from consideracted.	ition.			
Application Paper	s					
10) The drawi Applicant i Replacem	fication is objected to by the Examiner ng(s) filed on is/are: a) accemay not request that any objection to the cent drawing sheet(s) including the correction declaration is objected to by the Example.	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 l	J.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)  1) Notice of Referen		4) Interview Summary				
	erson's Patent Drawing Review (PTO-948) osure Statement(s) (PTO/SB/08) Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

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#### **DETAILED ACTION**

Applicants amendments to the claims have been entered. Any rejection from the previous office action filed 01/26/2007 not addressed below has been withdrawn.

#### Election/Restrictions

Applicant's election with traverse of Group I claims 1-12,15-16,18-26 and 69 in the reply filed on 10/11/2007 is acknowledged. The traversal is on the ground(s) that functionalizing a diamine into the corresponding isocyanate is not a recited method step in the claims. Also applicants assert that a search for groups I and II will require a search of the same art and points to the fact that the examiner searched for groups I and II in the previous action. Thus applicants surmise it would not be burdensome for the examiner to search the groups identified above. These arguments are not found persuasive because firstly applicants have amended their claims from the previous office action so that the multifunction isocyanate group is formed via amide conversion. This new limitation must be addressed in the method to produce the polyurethane (group II) but since it is a product by process type of limitation for the product claims (group I), the patentability is determined on the product itself not on the process of its manufacture. The examiner disagrees with applicant's statement that functionalizing a diamine into the corresponding isocyanate is not a recited method step in the claims; clearly this is a step in making the isocyanate which is then reacted with the bioactive agent. Since the claims are drawn to a method of producing a polyurethane any stepincluded in the claim language that is an active step in the process of manufacture must be treated as a limitation by the examiner.

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The requirement is still deemed proper and is therefore made FINAL.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-4,7-8,10,15-16,19 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Xiangjiao Gongye 1997, 20(4), 244, cited by applicants).

Chen teaches biodegradable polyurethanes modified by starch, the polyurethane was synthesized from the polyol poly(tetramethylene oxide), TDI (toluene diisocyanate) and starch which reads on the bioactive agent (polysaccharide) claimed by applicant. Regarding claims 3-4 starch and poly(tetramethylene oxide) each contain more than one hydroxyl group. Regarding the limitations within claim 1 on how the isocyanate is formed and within claims 7-8 which detail how the diisocyanate and bioactive come into contact with each other, these limitations are all product by process type of limitations, therefore since the product produced in Chen is the same as applicants claimed invention the limitations are considered met. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 10, since the scope of the active ingredient of Chen overlaps the actives of applicants claimed invention (polysaccharides) it is the position of the examiner that the same compound will have the same effects on the human body. Regarding the limitations within claims 15-16, starch besides reading on applicant's active agent is also a polyol that is a biomolecule, therefore it meets applicants limitations for claims 15-16.

Claims 1,3,7-8,10-12,19-22,27,34-35 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipatova et al. (Macromol. Symp. 152,139-150 (2000), cited previously).

Lipatova teaches hemocompatable (same as biocompatible) and biodegradable polyurethanes containing bioactive heparine fragments, which are prepared from diisocyanates, oligoetherglycols, chain extenders and heparin, which comprises a plurality of hydroxyl groups and has a therapeutic effect in the body. See pag 145-148 2<sup>nd</sup> paragraph. The biocompatible and biodegradable polyurethanes containing bioactive heparine fragments were used for the creation of artificial blood vessels. Regarding the limitations within claim 1 on how the isocyante is formed and within claims 7-8 which detail how the diisocyanate and bioactive come into contact with each other, these limitations are all product by process type of limitations, therefore since the product produced in Lipatova is the same as applicants claimed invention the limitations

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are considered met. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 3 heparin contains numerous hydroxyl groups. Regarding claim 11, Lipatova does anticipate a carbohydrate bioactive (heparin) but heparin also anticipates an anticancer agent as evidenced by the teaching of Niers et al. (Mechanisms of heparin induced anti-cancer activity in experimental cancer models, Crit. Rev. Oncol./Hematol. (2006), doi:10.1016/j.critrevonc.2006.07.007), cited previously. Neirs clearly notes that heparin demonstrated anti-cancer activity in animal tumors, thus heparin meets the limitation that the bioactive agent is an anticancer agent. See entire document.

### Response to Arguments

Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive.

Applicants assert that it is not apparent from Lipatova that the heparin itself is reacted with the multifunctional isocyanate. Applicants further assert that it would be impossible from the disclosure of Lipatova to ascertain if heparin would be a degradation product and how long such a degradation would take place and there is no disclosure within that heparin would be released into the body. Applicants further assert

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that heparin is incorporated in the polymer to improve hemocompatibility of the polymer itself and is not used for any biological effect after degradation. Applicants lastly assert that the new limitation which produces the multifunctional isocyanates from a biocompatible compound having two amine groups to isocyanate groups further differentiates their invention from Lipatova.

The relevance of these assertions is unclear. Applicant's claims are drawn to a polyurethane composition, therefore the patentability is determined on the product itself not on the process of its manufacture. Thus the starting material used to produce the diisocyantes and how the bioactive agent and isocyanates are reacted bear no weight on the patentability of the claimed subject matter if a product such as the polyurethanes of Liptova anticipates applicants claimed composition. Since Lipatova teaches polyurethane containing the bioactive heparin incorporated into its backbone, Lipatova anticipates applicants claimed invention. Regarding applicant's assertion that it would be impossible to determine if heparin would be a degradation product and if it would be released into the body, since Lipatova anticipates applicants claimed composition the examiner assumes that it must be capable of biodegrading and releasing the bioactive within a living organism. Besides the recitation that the polyurethane composition releases a bioactive agent within the body by degradation is an intended use type of limitation for the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language

Claims 1,3-12,15-16,19-20,22,25 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al. (US 7,264,823 B2).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Beckman teaches an adhesive containing the reaction product of a multifunctional isocyanate reactant and at least one multifunctional reactant that can be selected from PEG, steroids, polysaccharides, saccharides, polyamino-acids such as proteins and/or peptides; the polymeric network formed is biocompatible and biodegradable. See abstract, col 3 lin 14-col 4 lin 55 and claim 1. Regarding the

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limitation within claim 1 that the isocyanate is formed via conversion of two amine groups, the diisocyanate of Beckman was synthesized from lysine which contains two amine groups. Regarding claim 3 saccharides and polysaccharides contain numerous hydroxyl groups, thus meeting the claim limitation. Regarding claim 4 PEG is a polyol that contains two hydroxyl end groups, thus meeting the claim limitation. Regarding claims 5-6 Beckman teaches the use of a chain extender selected from tyrosine, lysine or tryptophan, all of which have at least two functional groups selected from hydroxyl or amine groups. See col 8 lin 56-col 9 lin 3. Regarding the limitations within claims 7-8 which detail how the diisocyanate and bioactive come into contact with each other, this limitation is a product by process type of limitations, therefore since the product produced in Beckman is the same as applicants claimed invention the limitations are considered met. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 10, since the scope of the active ingredients of Beckman overlaps the actives of applicants claimed invention (polysaccharides, peptides, proteins, steroids) it is the position of the examiner that the same compound will have the same effects on the human body. Regarding the limitations within claims 15-16, polysaccharides and saccharides besides reading on applicant's active agent are also polyols that are

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biomolecules, therefore applicants limitations for claims 15-16 are met. Regarding claim 20 it is inherent that since the peptides of Beckman are typically between 2-50 amino acids in length the peptide weight would fit within applicants broadly claimed MW. Regarding claim 22 Beckman's polymers did form foams, thus meeting the limitation of the claim. See col 8 lin 21-57. Regarding claim 25 Beckman teaches that the product has an average isocyanate functionality of at least 2.1, thus the ratio of NCO:OH must be greater than unity because there are still unreacted isocyanate groups left after the reaction of the diisocyanate with the multi-functional reactant.

Claims 1,3-4,7-8,12,19,22,27-30,33 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1, cited previously).

Woodhouse teaches biodegradable polyurethane materials synthesized from an amino acid based diisocyanate such as lysine, a polyol and an amino-acid chain extender (including more than one amino acid joined in a chain to form an oligopeptide). See col 2 lin 21-col 3 lin 30, col 6 lin 17-col 7 lin 5 and col 8 lin 20-39. The amino acids have a plurality of reactive amine groups. Regarding the limitations within claim 1 on how the isocyante is formed and within claims 7-8 which detail how the diisocyanate and bioactive come into contact with each other, these limitations are all product by process type of limitations, therefore since the product produced in Woodhouse is the same as applicants claimed invention the limitations are considered met. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not

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depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

## Response to Arguments

Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive.

Applicants assert that Woodhouse does not disclose or suggest reacting isocyanate groups of a least one diisocyanate with at least one bioactive compound. Applicants support this assertion by pointing to the embodiments within Woodhouse in which ester linkages are introduced adjacent to the amino-acids. Applicants also assert that the amino acids may be altered or destroyed during enzymatic recognition and thus not be released into the body upon degradation of the polymer. Applicants lastly assert that Woodhouse only specifically describes reaction/esterfication of L-phenylalanine and L-lysine and 1,4-cyclohexane dimethanol to form a chain extender for use in the polyurethanes. Therefore applicants surmise that Woodhouse is not enabling for the use of such oligopeptides or polyaminoacids in the polyurethanes thereof.

The relevance of these assertions is unclear. Woodhouse clearly recites that the polyurethane is formed by reaction of the diisocyanate with the chain extender which is an amino acid that contains free amino end units. It is inherent that since a reaction would form polyurethane the diisocyanate reacted with the end groups on the amino acid chain. The ester linkages which are introduced adjacent to the amino acid chain

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applicants are referring to is just one of several embodiments and does not limit the scope in its entirety for the disclosure of Woodhouse. Regarding applicant's assertion that the amino acids may be altered or destroyed when they are recognized by the enzyme, since Woodhouse anticipates applicants claimed composition the examiner assumes that it must be capable of biodegrading and releasing the bioactive within a living organism. Besides the recitation that the polyurethane composition releases a bioactive agent within the body by degradation is an intended use type of limitation for the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Regarding applicants assertion that Woodhouse only exemplifies esterfied chain extenders that include the amino acids, the examples within Woodhouse were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-12,15-16,18-26 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258, cited previously) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000), cited previously) or in view of Woodhouse et al. (US 6,221,997 B1, cited previously).

Zhang discloses biodegradable peptide-based urethane polymers synthesized by lysine diisocyanate (LDI) ethyl ester and glycerol (hydroxylated biomolecule) which were further reacted with water as the chain extender, forming foams for tissue

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engineering applications, the foams supported the growth of rabbit bone marrow stomal cells *in vitro*. See entire article. Regarding claim 23 the limitation of pore size is met by Zhang's discloser that the pore size can be 10 µm to 2 mm in diameter. See page 1252, right col. 2<sup>nd</sup> paragraph. Zhang disclosed that the free isocyanate content is 1.26% meeting the limitation on the free isocyanate content within claims 24 and 36. See page 1252 right col. 1<sup>st</sup> paragraph. Regarding claims 25-26 and 37-38 the NCO:OH equivalent limitations are met because Zhang discloses that 55 mmol of glycerol was added to 87 mmol of LDI, since LDI has two reactive sites (NCO) and glycerol has three (OH) the NCO:OH equivalent is 1.05.

Zhang while disclosing the peptide based urethane polymer may allow incorporation of proteins of interest such as cell attachment and/or growth factors does not give any working examples.

Liptova and Woodhouse are disclosed above. Woodhouse and Liptova are used to primarily show that it was already well known in the art at the time of the invention to incorporate bioactive ingredients (heparin and polyamino acids) into biodegradable polyurethane/polyol polymers.

Therefore it would have been obvious to one of ordinary skill in the art from the disclosure of Zhang to incorporate bioactive substances in the disclosed urethane. polymers and from the disclosures of Liptova and Woodhouse it would have been obvious that polyurethanes could be conjugated to bioactive substances such as peptides and heparin. Thus the claimed invention would have been *prima facie* obvious

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since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

## Response to Arguments

Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive.

Applicants assert that for the reasons addressed above in applicant's arguments over the 102 (b) rejection over Liptova that the reference cannot cure the deficiencies of Zhang.

Since the arguments are essentially the same as above the examiner incorporates his remarks from above herein. As cited above Litova does read on applicants claimed polyurethanes containing a bioactive agent.

# **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-4,7-12,15-16,19,25 and 69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,264,823 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1,3-4,7-12,15-16,19,25 and 69 are generic to all that is recited in claims 1 of U.S. Patent No. 7,264,823 B2. That is, claims 1 of U.S. Patent No. 7,264,823 B2. That is, claims 1 of U.S. Patent No. 7,264,823 B2 falls entirely within the scope of claims 1,3-4,7-12,15-16,19,25 and 69 or in other words, claims 1,3-4,7-12,15-16,19,25 and 69 are anticipated by claims 1 of U.S. Patent No. 7,264,823 B2. Specifically both while not being identical in that applicant's claims are drawn to a polyurethane composition while '823 claims a method of applying a composition, both recite a polymer formed from reacting a multifunctional isocyanate reactant with a multifunctional reactant, the reactants claimed as detailed in the 102(e) rejection over Beckman above overlap in scope. Thus applicant's claimed invention is obvious and unpatentable over claim 1 of U.S. Patent No. 7,264,823 B2.

#### Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

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whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER